Thomas Jefferson University
Informed Consent Document for Human Subjects Research – OHR-8
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Department: Emergency Medicine

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Medical Study Title: Focus groups to develop approaches to improve patient communication in times of diagnostic uncertainty.

Lay Study Title: A research study to learn from patients about how to best communicate with them in times when doctors are uncertain about the cause of their symptoms.

What Is Informed Consent

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans. Before a knowledgeable decision about whether to participate in a research study can be made, the possible risks and benefits related to the study should be understood. This process of learning and thinking about a study before deciding to participate is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form once the nature of the study is understood and a decision is made to participate. If there is anything about the study you don't understand or if there are questions, you should ask for explanations before signing this form;
- Being given a copy of the signed and dated consent form to keep.

What is the purpose of this study?

We want to teach doctors how to communicate better with patients when they are uncertain about a patient's diagnosis. We hope to use the information you tell us today to help create a program to teach this to doctors.

We are conducting focus groups, in which we are bringing together groups of participants to talk with them together in a conversation. This study does not involve any sort of treatment or therapy. It is not supposed to detect a disease or find something wrong. If you decide to

Thomas Jefferson University IRB
Approval Date 4/23/18
Expiration Date 8/15/18
Annual review due 6 weeks before expiration.

participate or not to participate there will be no loss of benefits to which you are otherwise entitled.

How many individuals will participate in the study and how long will the study last?
We hope to enroll **up to** 40 participants at Jefferson Health network and **up to** 80 participants nationally, into one of 8 focus groups. Each participant will be in the study for a two hour focus group.

What will happen during the study?
You will be asked to complete a short demographic survey and participate in a two hour focus group conversation with other individuals who have recently been a patient in the emergency room. During the focus group, we will ask for your ideas and understanding about issues related to diagnostic uncertainty, which refers to times that patients have symptoms but the doctors are unable to definitively give them a diagnosis (or cause) for these symptoms.

The group conversation will be audio recorded. If there are any questions that make you feel uncomfortable, you do not have to answer them. If at any point you feel uncomfortable, you are free to leave and without penalty. The audiotapes will be sent to a professional company that will type up the interview and then they will destroy their copy of the audiotape.

In addition to the focus group, we will also ask you to fill out a short demographic survey, which will ask about your age, ethnicity, race, gender, primary care doctor, healthcare utilization, marital status, number of people in household, primary language, education, ability to understand health information, employment, student status, household income, overall health rating, health insurance status, and recent emergency department discharge diagnosis.

As part of the study, we will also collect the following personal health information from your electronic medical record, to be used for research purposes:

- discharge diagnosis from Thomas Jefferson University Emergency Department
- discharge date of Thomas Jefferson University Emergency Department
- number of times you visited Thomas Jefferson's Emergency Department

Are there benefits from being in this study?
There will be no direct benefit to you from being in this research, but we hope that what we learn may be helpful to future patients or society in general.

Are there alternatives to being in the study?
Participation in this study is entirely voluntary. You can choose not to be in this study.

How will privacy and confidentiality (identity) be protected?
Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies an individual personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that people may see and review their medical records at any time. However, in a

research study, people may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

We will do our best to make sure that any personal information that you choose to disclose during the course of the focus group will be kept private. However, we cannot guarantee total privacy. We ask that participants keep information shared in the focus group confidential, however we cannot guarantee this confidentiality. All paper documents are secured in locked cabinets in a locked office accessible only to research personnel.

Audio recordings of the focus group will be sent to a professional transcription service. The transcription agency will be asked to remove all identifying information from the transcripts and destroy their copy of the audio files after transcription is complete. In order to keep your information private, you will be assigned a unique code number. A key containing each participant's name, study identification number, and contact information will be kept in locked file cabinets that can only be accessed by key study personnel or electronically on a password-protected, network-level-secured computer. This information will be kept in locked file cabinets until study procedures are completed and the data have been checked for completeness and accuracy. Data from this study will be destroyed seven years after all study procedures are complete.

The following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel of Thomas Jefferson University, Jefferson University Physicians, Thomas Jefferson University Hospitals, Inc., the University's Office of Human Research and the Institutional Review Board (IRB). In addition, we will share this information with investigators who we are working with at Northwestern University.

PHI collected during this study may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- ***Agency for Healthcare Research and Quality (AHRQ)*** which is providing funds to Thomas Jefferson University/Jefferson Health and Northwestern University to conduct this research
- With any person or agency required by law.

The following information will be provided to the study sponsor and other entities noted above:
Study data for analysis: transcripts from the focus group session
Demographic data provided by you: age, ethnicity, race, gender, primary care doctor, healthcare utilization, marital status, number of people in household, primary language, education, ability to understand health information, employment, household income, overall health rating, health insurance status, and recent emergency department discharge diagnosis

PHI collected as part of this research may be used/disclosed until the end of the research study. You may quit the study and revoke permission to use and share PHI at any time by contacting the

principal investigator, in writing, at:

Kristin Rising, MD, MS
1025 Walnut St, Suite 300
Philadelphia, PA 19107

Further collection of PHI will be stopped on those who quit the study, but PHI that has already been collected may still be used.

Is there payment for being in this study?
You will receive a $50 money card for completing the focus group.

Disclosure of Financial Interest
The sponsor of this clinical study, the Agency for Healthcare Research and Quality (AHRQ), is paying Thomas Jefferson University and Northwestern University to conduct this study.

Are there costs related to being in this study?
You will not have to pay anything to participate in the study.

Can I be removed from the study or quit the study?
You are being asked to volunteer for a two hour focus group. You are only asked to come and meet with us one time. We hope you stay for the entire time, but if you want or need to leave you are free to do so. Your participation will end after all participants have completed the focus group, and all the information has been collected.

Again you are free to leave the study at any time. That means you can leave the focus group during the session.

There is no penalty or loss of benefits to which you are otherwise entitled if you decide to leave the study.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	The Jefferson Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Kristin Rising, MD MS or any co-investigator listed at the beginning of this form	***215-503-5507***
If you have difficulty contacting the study staff	Call the Jefferson Office of Human Research	215-503-0203

If you want more information about the Jefferson Institutional Review Board or Jefferson's Human Research Protection Program, please visit their website at http://www.jefferson.edu/human_research/irb/index.cfm.

Non-Waiver of Legal Rights Statement

- ✓ **By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.**
- ✓ **In order to be in this research study, you must sign this consent form.**
- ✓ **You affirm that you have read this consent form. You have been told that you will receive a copy.**

SIGNATURES

_____

Your Name

_____

Your Signature Date

_____

Name of Person Conducting Consent Interview

_____

Signature of Person Conducting Consent Interview Date

☐ **Copy of Signed and Dated Consent Form Given to the Participant**

As Per University Counsel - Do Not Sign This Consent Form After 8/16/18